

**U.S.S.N 09/687,483**

**BRAUN *et al.***

**ELECTION AND PRELIMINARY AMENDMENT**

Claims 4-17, 30-34, 43-54, 60-64, 71-81, 83-85 and 98-100 are pending. Claims 1-3, 18-29, 35-42, 55-59, 65-70, 82, 86-97 are cancelled herein without prejudice or disclaimer. Applicant reserves the right to file a divisional application directed to any cancelled subject matter.

**TRAVERSAL OF RESTRICTION REQUIREMENT AND ELECTION OF SPECIES REQUIREMENT**

The Restriction Requirement is respectfully traversed as between Group II and Group V and as between Group II and Group XVI; the election of species requirement as it pertains to the elected group. In particular with respect Group II is related to each of Groups IV and XVI as a subcombination/combination for which a showing of two-way distinctness is required.

Inventions that are related as a combination and subcombination are distinct and restriction may be proper **only if** it can be shown that the combination as claimed does not require the particulars of the subcombination as claimed for patentability **and** that the subcombination has utility by itself or in other combinations. See MPEP 808.05(c).

Group II includes claims to a database. For example claim 8 recites:

8. A database, comprising:  
datapoints representative of a plurality of healthy organisms  
from whom biological samples are obtained,  
wherein each datapoint is associated with data  
representative of the organism type and other identifying information.

Claim 32 of Group V is directed to:

32. A system for high throughput processing of biological samples, comprising:  
a process line comprising a plurality of processing stations, each of which performs a procedure on a biological sample contained in a reaction vessel;  
a robotic system that transports the reaction vessel from processing station to processing station;  
a data analysis system that receives test results of the process line and automatically processes the test results to make a determination regarding the biological sample in the reaction vessel;

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- a control system that determines when the test at each processing station is complete and, in response, moves the reaction vessel to the next test station, and continuously processes reaction vessels one after another until the control system receives a stop instruction; and
- a database of claim 8, wherein the samples tested by the automated process line comprise samples from subjects in the database.

Claims 33 and 34 are dependent on claim 32, which is combination that includes the database of claim 8.

In this instance, the combination of claim 32, which includes a known automated process line (see, page 40 of the instant specification which states "[t]he computers and databases can be used in conjunction, for example, with the APL system (see, copending U.S. application Serial No. 09/285,481), which is an automated system for analyzing biopolymers"), requires the particulars of the database of claim 8 for patentability. Therefore, as between Group II and Group V restriction is **not** proper.

Similarly, Claim 100, Group XVI, recites:

- A system for high throughput processing of biological samples, comprising:
  - a database of claim 8, wherein the samples tested by the automated process line comprise samples from subjects in the database; and
  - a mass spectrometer for analysis of biopolymers in the samples.

Claim 100, which is directed to a combination of a database of claim 8 and a mass spectrometry, requires the particulars of the database of claim 8 for patentability. Therefore, as between Group II and Group XVI restriction is **not** proper.

**Election of species**

The elected group includes claim 8, discussed above, which is directed to a "healthy patient" database. The databases include data for the healthy patients that constitute the answers to questions. The subjects of the database are "healthy" subjects; it is the selection of such subjects as the source of data

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for a database that is the subject of the application and claims and that provides the results that information that can be obtained from the database. As defined in the application the database is:

As used herein, a healthy database (or healthy patient database) refers to a database of profiles of subjects that have not been pre-selected for any particular disease. For each subject the answers to the questions are pertinent to the ultimate use of the database, which is sorted according based upon each question. The questions posed to each subject include, for example, age, gender, height, weight, alcohol intake, number of pregnancies, number of live births, vegetarians, type of physical activity, state of residence and/or length of residence in a particular state, educational level, age of parent at death, cause of parent death, former or current smoker, length of time as a smoker, frequency of smoking, occurrence of a disease in immediate family (parent, siblings, children), use of prescription drugs and/or reason therefor, length and/or number of hospital stays and exposure to environmental factors. In all instances, however, the focus of the search is for a database in which the subjects are "healthy."

The Office has requested election of the answers to one of the questions and urges that this is a "species." It is respectfully submitted that such election does not make sense in the context of this database. The search should be directed to a search of databases to identify any in which the subjects of the database are selected because they do not exhibit any particular disease.

An election of species is designed to serve as search tool. An applicant elects a species for search and if the Office finds no pertinent art, it searches another species and continues to search different species, and eventually if none are found, the genus is allowed. In this instance, however, not matter which parameter is elected, the search must be directed to finding databases in which the source of the information is from "healthy" subjects as defined in the instant application. If no such database is found, then, claim 8 should be allowable. In addition, if claim 8 is found allowable, then every method claim as well as the combination claims (discussed above) that depend upon claim 8 (or depends thereof) must be allowable. Therefore, non-elected claims that depend upon claim 8 are retained herein.

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In view of the above remarks, reconsideration of the restriction requirement and examination of the application on the merits are respectfully requested.

Respectfully submitted,  
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